File date 8/3/17 2:27 PM

IN THE CIRCUIT COURT OF THE STATE OF OREGON

FOR THE COUNTY OF MULTNOMAH

COUNTY OF MULTNOMAH, Plaintiff, vs. PURDUE PHARMA, LP, a Delaware limited partnership; PURDUE PHARMA, INC., a New York corporation; THE PURDUE FREDERICK COMPANY, INC., a Delaware Corporation; TEVA PHARMACEUTICAL INDUSTRIES, LTD., an Israeli corporation; TEVA PHARMACEUTICALS USA, INC., a Delaware corporation; CEPHALON, INC., a Delaware corporation; JOHNSON & JOHNSON, a New Jersey corporation; JANSSEN PHARMACEUTICALS, INC., a Pennsylvania corporation; ENDO HEALTH SOLUTIONS, INC., a Delaware corporation; ENDO PHARMACEUTICALS, INC., a Delaware corporation; ALLERGAN PLC an Irish public limited company; ACTAVIS PLC, an Irish public limited company; WATSON PHARMACEUTICALS, INC., a Nevada corporation; ACTAVIS, INC., a Nevada corporation; WATSON LABORATORIES, INC., a Nevada corporation; ACTAVIS LLC, a Delaware limited liability corporation; ACTAVIS PHARMA, INC., a Delaware corporation; WATSON PHARMA, INC., a Delaware corporation; MALLINCKRODT PLC, an Irish public limited corporation; INSYS THERAPEUTICS, INC., a Delaware corporation; MCKESSON CORPORATION	Case No. 17CV33413 COMPLAINT Public Nuisance, Abnormally Dangerous Activity, Gross Negligence, Fraud & Deceit, and Negligence DAMAGES: $250,000,000.00 Filing Fee: $1,056.00 CLAIM NOT SUBJECT TO MANDATORY ARBITRATION Jury Trial Requested

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dba MCKESSON DRUG COMPANY, a Delaware corporation; AMERISOURCEBERGEN DRUG CORPORATION, a Delaware Corporation; CARDINAL HEALTH, INC., a Delaware corporation; JULIE ANN DEMILLE, an Oregon citizen; FUSION WELLNESS CLINIC, an Oregon business; ROY BLACKBURN, M.D., an Oregon citizen; OREGON TLC, LLC, an Oregon limited liability corporation; OREGON TLC, S – CORPORATION, an Oregon S-corporation; PACIFIC MEDICAL EVALUATION AND REVIEW COMPANY, an Oregon corporation; JAMES GALLANT, M.D., an Oregon citizen; CORVALLIS INTERNAL MEDICINE, P.C., an Oregon professional corporation; GALLANT INTERNAL MEDICINE, P.C., an Oregon professional corporation; STUART ROSENBLUM, M.D., an Oregon citizen; STUART M. ROSENBLUM, M.D., LLC, an Oregon limited liability corporation; and DOES 1 THROUGH 100 INCLUSIVE;

Defendants.

Plaintiff County of Multnomah ("Multnomah County," "County," or "Plaintiff") alleges:

I. INTRODUCTION

1.

As a matter of common sense and medical evidence, long-term use of opioids—drugs that can kill you or commit you to a lifetime of addiction—does not improve function or quality of life. To the contrary, if it does not kill you, long-term use of opioids will cause disability, disease, and distress.

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A. A *Man-Made, Profit-Driven Public Health Crisis/Epidemic*

2.

"Drug overdose deaths have become the leading cause of injury death in the United States, surpassing the number of deaths by motor vehicles and by firearms every year since 2008. Overdose deaths, particularly from prescription drugs and heroin, have reached epidemic levels."[1]

3.

The DEA calls it an "epidemic."[2] The FDA calls it an "epidemic and a "public health crisis" that has a "profound impact on individuals, families and communities across our country."[3] And the Surgeon General refers to it simply as: "The Opioid Crisis."[4]

4.

Whether you call it a crisis or an epidemic, it is clear that the cause is man-made and that the motive is money.

5.

Drug companies should never place their desire for profits above the health and well-being of their customers or the communities where those customers live. Because they know prescribing doctors and other health-care providers rely on drug companies' statements in making treatment decisions, drug companies must tell the truth when marketing their drugs and ensure that their marketing claims are supported by science and medical evidence.

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[1] Rosenberg, Chuck, Acting DEA Administrator, *National Drug Threat Assessment Summary*, (October 2015) (available at https://www.dea.gov/docs/2015%20NDTA%20Report.pdf.)

[2] *Id.*

[3] *FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death*, FDA News Release (Mar. 22, 2016) (available at: https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm); *see also, FDA requests removal of Opana ER for risks related to abuse*, FDA News Release (June 8, 2017) ("[w]e are facing an opioid epidemic—a public health crisis, and we must take all necessary steps to reduce the scope of opioid misuse and abuse") (available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm).

[4] *Facing Addiction In America,* The Surgeon General's Report on Alcohol, Drugs, and Health, (2016) (available at: https://addiction.surgeongeneral.gov/executive-summary.pdf).

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6.

Drug-Maker Defendants (as defined below) broke these simple rules and helped create and fuel a healthcare crisis that has had far-reaching financial, social, and deadly consequences in Multnomah County, Oregon.

7.

Drug-Maker Defendants manufacture, market, and sell prescription opioids (hereinafter "opioids"), including brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone, which are powerful narcotic painkillers. Historically, because they were considered too addictive and debilitating for the treatment of chronic pain (like back pain, migraines and arthritis), opioids were used only to treat short-term acute pain or for palliative (end-of-life) care.

8.

However, by the late 1990s, and continuing today, Drug-Maker Defendants began a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, a far broader group of patients much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, Drug-Maker Defendants spent, and continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

9.

As to the risks, Drug-Maker Defendants falsely and misleadingly, and contrary to the language of their drugs' labels:

(a) Downplayed the serious risk of addiction.

(b) Promoted the concept of "pseudoaddiction" and thus advocated that the signs

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of addiction should be treated with more opioids.

(c) Exaggerated the effectiveness of screening tools in preventing addiction.

(d) Claimed that opioid dependence and withdrawal are easily managed.

(e) Denied the risks of higher opioid dosages.

(f) Exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

(g) Conversely, Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no "good evidence" to support Defendants' claims.

10.

Drug-Maker Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians Drug-Maker Defendants recruited for their support of Drug-Maker Defendants' marketing messages. Borrowing a page from Big Tobacco's playbook, Drug-Maker Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). Drug-Maker Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Drug-Maker

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Defendants persuaded doctors and patients that what they had long known—that opioids are addictive drugs, unsafe in most circumstances for long-term use—was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

11.

Each Drug-Maker Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Drug-Maker Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA ("2016 CDC Guideline"). Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into settlements agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint in other jurisdictions. Yet even now, each Drug-Defendant continues to misrepresent the risks and benefits of long-term opioid use in Multnomah County, Oregon and continues to fail to correct its past misrepresentations.

12.

Drug-Maker Defendants' efforts were wildly successful. Opioids are now the most prescribed class of drugs; they generated $11 billion in revenue for drug companies in 2014 alone. Unsurprisingly, since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled. In 2010, some 254 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month. In that year, 20% of all doctors' visits resulted in the prescription of an opioid (nearly double the rate in 2000). While Americans represent only 4.6% of the world's population, they consume 80% of the

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opioids supplied around the world and 99% of the global hydrocodone supply. By 2014, nearly two million Americans either abused or were dependent on opioids.

13.

Defendants' business model is based on addiction. 47% of patients on opioids for 30 days during a year will still be on opioids 3 years later.[5] 60% of patients on opioids for 3 months will still be on opioids 5 years later.[6] And 100% of patients that chronically use opioids will become dependent.[7] Over 280 million opioid pills were distributed in Oregon in 2016.[8] These numbers foretell a terrible continuation if not worsening of the opioid epidemic.

B. ***Plaintiff Multnomah County's Fight Against Defendants' Man-Made, Profit-Driven Public Health Crisis / Epidemic***

14.

Regardless of whether you call it a crisis or an epidemic, Multnomah County is on the front lines of the fight against it. And that fight costs this community dearly. In lives shattered and lost. And, in public money spent in a seemingly endless fight.

15.

Multnomah County is the sole public health authority in the most populous county in the State of Oregon. In that role, Multnomah County provides funds for services, offered directly and indirectly through community partners, to help people affected by the opioid epidemic. Among other things, those services include the following:

(a) Opioid addiction treatment and rehabilitation

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[5] Nowak, M.D., Jo-Ellen Abou Nader CFE, CIA, CRMA, and Glen Stettin, M.D., *A Nation in Pain, Focusing on U.S. Opioid Trends for Treatment of Short-Term and Longer-Term Pain*, An Express Scrips Report, (Dec. 2014) (available at http://lab.express-scripts.com/publications/~/media/d48ef3ee579848e7bf3f14af536d7548.ashx).

[6] *Id.*

[7] *Id.*

[8] *See, New data reveals Oregon's opioid epidemic still dire in rural counties* (available at: http://www.kgw.com/news/investigations/opioid-prescriptions-drop-in-oregon-but-rural-counties-still-struggling-to-fight-addiction/456530917).

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(b) Primary health clinics

(c) Transitional housing

(d) Homeless services

(e) Mental health counseling

(f) Syringe exchange

(g) Distribution of Naloxone and training for its use

(h) Medication-assisted treatment

(i) Outreach and education

16.

Multnomah County spends millions of dollars each year to provide or pay for the health care, pharmaceutical care, and other necessary services and programs on behalf of indigents and otherwise eligible residents, including payments for prescription opium-like painkillers ("opioids"), which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants named below.

17.

In the Tri-County Area, Multnomah County has the highest proportion of Health Share clients in Medically Assisted Treatment.

18.

Because of Multnomah County's syringe exchange program, there has not been a significant spike in HIV and Hepatitis-C transmissions that other communities have faced nationally.[9] Nonetheless, intravenous drug use caused by the opioid epidemic necessarily leads to the spread of HIV and Hepatitis-C and further taxes limited Multnomah County resources spent on those diseases. Multnomah County spends scarce public resources

[9] *See HIV Outbreak in Southeastern Indiana* (available at: https://secure.in.gov/isdh/26649.htm).

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providing new syringes and discarding used syringes as part of its fight against the opioid epidemic.

19.

More than 50% of people using the syringe exchange program reported getting hooked on pain pills before switching to heroin.[10] Nationally, 80% of heroin users started by using prescription opioid pain pills.[11]

20.

Multnomah County runs the adult and juvenile corrections facilities in the County. All law enforcement within Multnomah County, including the Multnomah County Sheriff's Office as well as the municipal police for the cities of Portland, Fairview, Gresham, Troutdale, and Wood Village, use those facilities. In that role, Multnomah County provides funding for the following services, among other things, that are directly related to the opioid crisis:

(a) Booking and release

(b) Corrections facilities

(c) Corrections officers and staff

(d) Corrections-based drug treatment

(e) Corrections-based mental health counseling

(f) Corrections-based health care

[10] *Tri-County Opioid Trends*, *Clackamas, Multnomah, and Washington, Oregon* (2016) (available at: https://portlandprofessional.oregonpainguidance.org/wp-content/uploads/sites/8/2017/02/TRI-COUNTY-REGION-OPIOID-TRENDS-2016-REPORT.pdf).

[11] Statement of Michael P. Botticelli, Director of National Drug Control Policy, to the Committee on Oversight and Government Reform United States House of Representatives, *The Epidemic of Prescription Drug and Heroin Abuse in the United States*, (March 22, 2016) (available at: https://oversight.house.gov/wp-content/uploads/2016/03/Botticelli-ONDCP-Statement-3-22-Heroin-Opioid-Abuse.pdf); and Pradip K. Muhuri, Joseph C. Gfroerer, M. Christine Davies, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CBHSQ Data Review (Aug. 2013)(available at: http://archive.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf).

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21.

More than half of all people brought to the Multnomah County jail have substance abuse problems. Many of those people must be treated upon arrival for acute opioid withdrawals, infections that stem directly from opioid use, among other opioid related ailments.

22.

Multnomah County provides public safety services through the Multnomah County Sheriff's Department and emergency medical response services both of which respond to opioid related criminal and medical emergencies.

23.

Multnomah County runs community corrections programs to supervise probationers and parolees that have committed opioid related crimes as well as former criminals suffering from opioid addiction.

24.

Multnomah County also provides a wide range of other services to people in need, all of which have been taxed in the fight against the opioid epidemic. And, the fact of opioid addiction makes helping people in need more difficult and costly.

25.

Not even Multnomah County's public libraries are untouched by the epidemic. In library restrooms, staff must handle syringes left behind and blood on the floors. Multnomah County now has social workers at libraries to help people in crisis. And staff have requested Naloxone training to be able to address the eventuality of opioid overdoses in public libraries.

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26.

As a direct and foreseeable consequence of the Defendants' wrongful conduct, detailed more fully below, Multnomah County has been required to spend millions of dollars each year in their efforts to combat the public nuisance created by Defendants. Multnomah County incurred and continues to incur costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs, as well as direct injuries to Multnomah County's economy which were proximately caused by Defendants' tortious acts and practices. Additionally, Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Multnomah County and its residents. The tortious acts of all Defendants, detailed more fully below, have directly and proximately caused injury and damage to Multnomah County and its residents.

27.

Defendants, and each of them, knew that long-term opioid use causes addiction. Nonetheless, driven by the potential for incredible profits, Defendants engaged in a comprehensive campaign of lies and deceptions to overturn centuries-old, accurate scientific, historical, and conventional knowledge about the risks of long-term opioid use. Through their lies and deception Defendants effectively promoted the long-term use of opioids even though there was no scientific basis to support that use. Defendants' comprehensive campaign of lies and deceptions caused opioid addiction to increase exponentially. And that increase has required Multnomah County to expend its limited resources to help those affected and protect the community from harms associated with the opioid epidemic.

28.

All told, Multnomah County has been forced to spend more than $100,000,000.00

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fighting the opioid epidemic. Through this civil action, Multnomah County seeks $100,000,000.00 in economic damages to repay it for the past costs associated with abating the opioid epidemic caused by Defendants.

29.

Defendants' tortious conduct is continuing. Multnomah County's past damages have not occurred all at once and they increase as time progresses. Multnomah County continues to be injured. Defendant's wrongdoing has not ceased.

30.

To effectively fight the opioid epidemic, Multnomah County will need to spend significantly more money than it does now on treatment and prevention programs. Through this civil action, Multnomah County seeks $150,000,000.00 in future economic damages to pay for the future costs of abating the opioid epidemic caused by Defendants.

31.

As authorized by ORS 31.725, Plaintiff reserves its right to amend this complaint to add claims for punitive damages.

II. CIVIL CONSPIRACY

32.

Defendants, and each of them, committed repeated tortious acts, in concert with each other or pursuant to a common design, and fraudulently concealed their misconduct. Each class of Defendants was an integral part of a scheme to create a vast population of addicts dependent on their product. This scheme could not work if one class of Defendants refused to participate. Opioids do not reach the public if drug companies do not manufacturer them, middlemen do not distribute them, pharmacies do not sell them, and doctors do not prescribe them. Inherent to this scheme's success is the imprimatur of legitimacy that comes along

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with doctors, pharmacists, and Fortune 500 companies saying that opioids are safe and non-addictive. Therefore, Defendants, and each of them, are jointly liable for the each other's tortious conduct and resulting damages described herein.

III. PARTIES, JURISDICTION, & VENUE

A. *Plaintiff*

33.

Multnomah County is an existing county government duly formed under the laws of the State of Oregon and is a body politic and corporate. The Multnomah County Board of Commissioners is duly elected to exercise the powers of Multnomah County and has approved the filing of this lawsuit.

34.

Multnomah County brings this civil action to protect and promote the public health and safety of its citizens against the reprehensible and tortious conduct of Defendants. Defendants acted as part of a vast conspiracy to fraudulently undermined scientific understanding about the dangers of opiates with the goal of promoting widespread use of highly addictive pharmaceutical opioids for inappropriate, improper, or unsafe uses. The now decades-old opioid epidemic shows the incredible success of Defendants' conspiracy.

35.

Multnomah County has authority to bring this civil action, under the Constitution of the State of Oregon, Oregon Revised Statutes, The Multnomah County Charter, and under the common-law principle of *parens patriae*. Multnomah County has the right to recover the economic harms it has suffered directly and to protect the public interest by redressing and abating the direct physical injuries suffered by Multnomah County's residents and caused by Defendants—physical injuries the direct treatment of which cost Multnomah County greatly

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and form the largest part of Multnomah County's direct economic harms.

36.

On July 27, 2017, the Multnomah County Board of Commissioners voted unanimously declaring an on-going public nuisance related to the improper and wrongful supply and distribution of prescription opioid pain pills in Multnomah County.

B. ***Drug-Maker Defendants***

37.

Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

38.

Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

39.

The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut.

40.

Purdue Pharma L.P., Purdue Pharma Inc. and The Purdue Frederick Company (collectively, "Purdue") manufacture, promote, sell, and distribute opioids nationally and in Multnomah County, including:

(a) OxyContin

(b) MS Contin

(c) Dilaudid/Dilaudid HP

(d) Butrans

(e) Hysingla ER

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(f) Targiniq ER

41.

OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

42.

On May 8, 2007, Purdue entered an agreed final judgment with the State of Oregon and 25 other states for $19.5 million, based principally on Purdue's direct promotion of OxyContin up to the effective date of the Final Judgment on May 8, 2007. Days later, Purdue and its top executives agreed to pay $634.5 million to end a United States Department of Justice case. More recently, in 2016, Purdue settled with the state of Kentucky for $24 million.

43.

The Purdue Frederick Company, Inc. is a convicted felon and admitted liar.

44.

On May 19, 2007, The Purdue Frederick Company, Inc., entered a plea of guilty to Count One of an Information charging it with the felony of misbranding of OxyContin, a prescription opioid pain medication, with the intent to defraud or mislead. The Information to which Purdue plead guilty charged, among other things, that:

> Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications as follows:
>
> Trained PURDUE sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the

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purpose of intravenous abuse, although PURDUE's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe;

Told PURDUE sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;

Sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;

Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and

Told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.[12]

Purdue has agreed that these facts are true, and the individual defendants, while they do not agree that they had knowledge of these things, have agreed that the court may accept these facts in support of their guilty pleas.[13]

45.

According to the Plea Agreement, "PURDUE is pleading guilty as described above because PURDUE is in fact guilty * * *."[14] The Court noted that "there exists aggravating circumstances of a kind, or to a degree, not adequately taken into consideration by the Sentencing Commission in formulating the guidelines" and then imposed the maximum statutory fine allowed.[15]

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[12] Information at ¶ 19, *United States of America v. The Purdue Frederick Company, et al.*, Case No. 1:07CR00029.
[13] Agreed Statement of Fact at ¶ 46, *United States of America v. The Purdue Frederick Company, et al.*, Case No. 1:07CR00029 (*available at* http://i.bnet.com/blogs/purdue-agreed-facts.pdf).
[14] Plea Agreement at p. 2, *United States of America v. The Purdue Frederick Company, et al.*, Case No. 1:07CR00029 (*available at http://lib.law.virginia.edu/Garrett/plea_agreements/pdf/purduefrederick.pdf*).
[15] *Id.*

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46.

In addition, three executive officers of Purdue Michael Friedman (former President and CEO of Purdue), Howard R. Udell (Executive Vice President and Chief Legal Officer), and Paul D. Goldenheim (former Chief Science Officer) all pleaded guilty to the misdemeanor charge of misbranding. Faced with punishment of twelve-months imprisonment and a fine of up to $100,000, these executives agreed to pay a total of $34.5 million. President and CEO Friedman agreed to pay $19 million, Executive Vice President and Chief Legal Officer Udell agreed to pay $8 million and Chief Science Officer Goldenheim agreed to pay $7.5 million. In return, the government agreed to sentence each without any imprisonment.

47.

Purdue transacts business in Oregon, targeting the Oregon market for its products, including the opioids at issue in this lawsuit. Purdue directs advertising and informational materials as well as marketing and sales tactics to impact Oregon physicians and potential users of Purdue products. Purdue has sustained, continuous business activity in Multnomah County, Oregon.

48.

Defendant Teva Pharmaceutical Industries, Ltd., ("Teva, Ltd.") is an Israel company with its corporate headquarters in Petah Tikva, Israel.

49.

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Whales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Ltd.

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50.

Defendant Cephalon, Inc. ("Cephalon, Inc.") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon.

51.

Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon, Inc. products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon, Inc. in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon, Inc.. Teva USA sells all former Cephalon, Inc. branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon, Inc. opioids marketed and sold in Oregon, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in Oregon, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon, Inc.'s promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon, Inc.'s and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon, Inc. acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon, Inc.'s specialty sales." Through interrelated operations like these, Teva Ltd. operates in Oregon and the rest of the United States through its subsidiaries Cephalon, Inc. and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd.

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directs the business practices of Cephalon, Inc. and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder.

52.

Teva, Ltd., Teva USA, and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of opioids nationally and, more particularly, in Multnomah County, including the following:

(a) Actiq

(b) Fentora

53.

Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and, more particularly, in Multnomah County.

54.

Cephalon, like Purdue, is also a convicted criminal and admitted liar.

55.

In 2008, Cephalon pled guilty to criminally violating the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million, $40 million of which was a criminal fine and $10 million a criminal forfeiture. In the plea agreement, Cephalon stipulated to a factual basis sufficient to support the entry of the plea.[16] As the government pointed out, if the case were to have proceeded to trial, the government was prepared to prove beyond a reasonable doubt:

(a) A concerted plan to maximize revenue by the off-label marketing of Actiq;

(b) Cephalon's unlawful promotional efforts included several facets, as set forth

[16] Guilty Plea Agreement, *U.S. v. Cephalon, Inc.*, Criminal No. 08-598 (E.D. Penn. 2008) (*available at* https://www.justice.gov/civil/file/892071/download).

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in the information, including training and compensating the sales staff to encourage off-label marketing, managing them to conduct this off-label marketing, co-opting the supposedly neutral continuing medical education process, and bestowing favors on doctors in the form of "consulting" sessions at lavish resorts where they attended off-label sessions. In fact, according to a Cephalon document, these meetings "proved incredibly effective in driving prescription growth among the attendees;"

(c) Cephalon's off-label marketing was no accident. Indeed, the proof would demonstrate that, for over six years, the very top levels of the company knew and approved of these efforts. This was a highly organized and deliberate effort to maximize revenue despite legal restrictions;

(d) The case of Actiq was particularly egregious, as this drug is 80-100 times more powerful than morphine. The FDA-approved label for Actiq is unusually restrictive:

> [Actiq] must not be used in opioid non-tolerant patients. Life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates. Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

The label calls for Actiq to be prescribed by oncologist or pain specialists familiar with the use of opioids. Because of the potency and risk of the drug, the FDA also mandated a risk management program requiring Cephalon to submit quarterly reports concerning issues such as diversion;

(e) In about 2001, Cephalon began a significantly expanded marketing effort for Actiq, including telling its sales representatives to target non-cancer physicians. In its marketing strategy for 2002, Cephalon described the

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Actiq patient profile as:

> any opioid tolerant patient suffering from breakthrough pain, regardless of disease state, is a potential candidate for Actiq. Additionally any patients suffering from moderate to severe episodic pain due to migraine headaches, sickle cell pain crises, etc. are potential candidates for Actiq. Lastly, Actiq may also be appropriate as a pre-procedural pain medication for any opioid naive or opioid tolerant patient about to undergo radiation therapy, wound dressing changes, physical therapy, etc. in a monitored setting.... By illustrating the true onset of analgesia and proving Actiq safe and effective in the treatment of other pain diagnoses, including both opioid tolerant and opioid naive patients, Actiq will be posed for tremendous growth in 2002 in both the BTP [breakthrough pain] and episodic pain segments of the opioid market.

(Emphasis added.) The marketing of Actiq for patients who were "opioid naive" directly contradicted the label and increased the risk for this population considerably;

(f) Cephalon management conveyed its disregard for the FDA-approved label for Actiq (opioid-tolerant cancer patients with breakthrough cancer pain, to be prescribed by oncologist or pain specialists familiar with opioids) to the sales force. Using the mantra "pain is pain," Cephalon instructed the sales representatives to focus on physicians other than oncologists, and to promote Actiq for multiple uses other than breakthrough cancer pain;

(g) These off-label promotions, directed by Cephalon caused patient harm, raised safety issues, and affected the proper treatment of patients. Cephalon undertook these promotions for its own gain, despite the risk to patients' health and lives.[17]

[17] *See Id.*; *see also,* Information, *U.S. v. Cephalon, Inc.*, Criminal No. 08-598 (E.D. Penn. 2008) (*available at* https://www.justice.gov/civil/file/892066/download); *and* Gov't's Memo. For Entry of Plea and Sentencing, *U.S. v. Cephalon, Inc.*, Criminal No. 08-598 (E.D. Penn. 2008) (*available at* https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonsentencingmemo.pdf).

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56.

Teva, Ltd, Teva USA, and Cephalon, Inc. transact business in Oregon, targeting the Oregon market for its products, including the opioids at issue in this lawsuit. Teva, Ltd, Teva USA, and Cephalon, Inc. direct advertising and informational materials as well as marketing and sales tactics to impact Oregon physicians and potential users of Cephalon products. Teva, Ltd, Teva USA, and Cephalon, Inc. have sustained, continuous business activity in Multnomah County, Oregon.

57.

Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

58.

Defendant Janssen Pharmaceuticals, Inc., formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc., a wholly-owned subsidiary of Johnson & Johnson, is a Pennsylvania corporation with is principal place of business in Titusville, New Jersey.

59.

Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

60.

Janssen Pharmaceutica, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

61.

Johnson & Johnson is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon

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information and belief, Johnson & Johnson controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to Johnson and Johnson's benefit.

62.

Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and, more particularly, in Multnomah County, including the following:

(a) Duragesic

(b) Nucynta

(c) Nucynta ER

63.

In 2014, Janssen made $172 million from sales of Nucynta and Nucynta ER. Prior to 2009, Duragesic accounted for at least $1 billion of Janssen's annual sales.

64.

Janssen transacts business in Oregon, targeting the Oregon market for its products, including the opioids at issue in this lawsuit. Janssen directs advertising and informational materials as well as marketing and sales tactics to impact Oregon physicians and potential users of Janssen products. Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. have sustained, continuous business activity in Multnomah County.

65.

Defendant Endo Health Solutions, Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

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66.

Defendant Endo Pharmaceuticals, Inc. is a wholly- owned subsidiary of Endo Health Solutions, Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

67.

Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. (collectively, "Endo") manufacture, promote, distribute and sell opioids nationally and, more particularly, in Multnomah County, including the following:

(a) Opana ER

(b) Opana

(c) Percodan

(d) Percocet

68.

Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Opana ER has recently been ordered removed from the market by the FDA.

69.

Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Oregon, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

70.

Endo transacts business in Oregon, targeting the Oregon market for its products, including the opioids at issue in this lawsuit. Endo directs advertising and informational

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materials as well as marketing and sales tactics to impact Oregon physicians and potential users of Endo products. Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. have sustained, continuous business activity in Multnomah County, Oregon.

71.

Defendant Allergan Plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Defendant Actavis Plc acquired Defendant Allergan plc in March 2015, and the combined company changed its name to Allergan Plc in January 2013. Before that, Defendant Watson Pharmaceuticals, Inc. acquired Defendant Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis Plc in October 2013. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Defendant Allergan Plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Defendant Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Defendant Allergan Plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Defendant Allergan Plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit.

72.

Defendants Allergan Plc, Actavis Plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are collectively referred to as "Actavis." Actavis manufactures, promotes, sells, and distributes

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opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. and Oregon. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009. Actavis transacts business in Oregon, targeting the Oregon market for its products, including the opioids at issue in this lawsuit. Actavis directs advertising and informational materials as well as marketing and sales tactics to impact Oregon physicians and potential users of Actavis products. Defendants Allergan Plc, Actavis Plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. have sustained, continuous business activity in Multnomah County, Oregon.

73.

Defendant Mallinckrodt Plc ("Mallinckrodt") is an Irish public limited company with its corporate headquarters in Staines-upon-Thames, United Kingdom and maintains a U.S. headquarters in St. Louis, Missouri. In Oregon and nationally, Mallinckrodt is engaged in the manufacture, promotion, and distribution of Roxicodone and Oxycodone among other drugs.

74.

Mallinckrodt is one of the largest generic manufacturers of oxycodone.

75.

Mallinckdrodt has agreed to settle claims brought by the Department of Justice that it shipped more than 500 million of its oxycodone pills into Florida between 2008 and 2012 (66% of the total in the state). Many of those pills were diverted and sold into the black market.

76.

Mallinckrodt transacts business in Oregon, targeting the Oregon market for its

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products, including the opioids at issue in this lawsuit. Mallinckrodt also directs advertising and informational materials as well as marketing and sales tactics to impact Oregon physicians and potential users of Mallinckrodt products. Mallinckrodt has sustained, continuous business activity in Multnomah County, Oregon.

77.

Defendant INSYS Therapeutics, Inc. ("INSYS") is a Delaware Corporation with its principal place of business in Phoenix, AZ. INSYS transacts business in Oregon, targeting the Oregon market for its products, including the opioids at issue in this lawsuit. INSYS directs advertising and informational materials as well as marketing and sales tactics to impact Oregon physicians and potential users of INSYS products. INSYS Therapeutics, Inc. has sustained, business activity in Multnomah County, Oregon.

78.

On Jul 10, 2015, INSYS received an unlawful trade practices and proposed solution letter from the Oregon Department of Justice. The letter documents the unlawful behavior of INSYS and three Oregon physicians: Roy Blackburn, MD of Tigard, Oregon, James Gallant, MD of Covallis, Oregon; and Stuart Rosenblum, MD of Portland, Oregon. INSYS paid the Oregon Department of Justice $1.1 million to settle the matter.

79.

The Oregon Department of Justice cited INSYS over following conduct:

(a) Implicitly misrepresenting to patients that Subsys should be used to treat migraine, neck pain, back pain, and other off-label uses for which Subsys is neither safe nor effective. This implicit misrepresentation occurred when you paid patients' insurance co-payments even when you knew the prescription was off-label or contraindicated; when you arranged for free Subsys to be provided

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to patients even when you knew the free product was for an off-label or contraindicated use; and when you advocated to obtain insurance payments to patients for Subsys when you knew Subsys was to be used for an off-label or contraindicated use.

(b) Implicitly misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other off-label uses for which Subsys is neither safe nor effective.

(c) Implicitly misrepresenting that the doctor whom you paid to teach Oregon physicians about Subsys was qualified to prescribe and teach about Subsys when in fact, he was not qualified.

(d) Misrepresenting that a paper written by a well-known doctor supported the definition of break through cancer pain used by you to promote Subsys when in fact, the paper did not support the definition.

(e) Misrepresenting that Subsys should be used to treat mild breakthrough cancer pain when in fact, the potential harm of using Subsys to treat mild pain far outweighs any possible benefit.

(f) Employing an unconscionable tactic by making payments to doctors that you intended to be a kickback to incentivize the doctor to prescribe Subsys.

(g) Employing an unconscionable tactic by targeting Subsys promotion at doctors whom you knew, or should have known, misprescribed Schedule II opioid drugs such as Subsys.

(h) Employing an unconscionable tactic by targeting doctors for Subsys promotion when you knew, or should have known, that the doctor only prescribed Subsys for off-label uses for which Subsys is neither safe nor effective.

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(i) Employing an unconscionable tactic by arranging for free Subsys to be provided to patients, and paying patients insurance co-payments for off-label uses of Subsys that you knew, or should have known, were neither safe nor effective.

(j) Employing an unconscionable tactic by pressuring sales representative to solicit doctors to shorten the label mandated titration schedule designed to protect patients.[18]

80.

Purdue, Cephalon, Janssen, Endo, Actavis, Mallinckrodt, and INSYS are collectively referred to herein as "Drug-Maker Defendants," because they engaged in the development, manufacture, promotion, sale, and distribution of opioids.

81.

Defendant Roy Manell Blackburn, III, MD, ("Dr. Blackburn") Medical License No. MD22132 is a practicing physician in the state of Oregon whose office addresses are 132 East Broadway, Suite 314, Eugene, OR 97401 and 2401 River Rd., Eugene, OR 99404.

82.

At all material times, Dr. Blackburn acted both individually and as an actual agent or apparent agent of INSYS.

83.

Defendant Oregon TLC, LLC ("TLC LLC") is an Oregon LLC with is principal place of business 132 East Broadway, Suite 314, Eugene, OR 97401. Dr. Blackburn is a member of Oregon TLC.

[18] *See, Testimony of David Hart, Oregon Department of Justice Office of the Oregon Attorney General to the United States Senate Committee on Finance*, (Feb. 23, 2016) (*available at* https://www.finance.senate.gov/imo/media/doc/23feb2016Hart.pdf).

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84.

Defendant Oregon TLC, S-Corporation ("TLC S-Corp") is an Oregon S-corporation with its principal place of business 132 East Broadway, Suite 716, Eugene, OR 97401. Dr. Blackburn is the President.

85.

Defendant Pacific Medical Evaluation and Review Company ("Pacific Med Eval") is an Oregon corporation with its principal place of business at 132 East Broadway, Suite 314, Eugene, OR 97401.

86.

On information and belief, TLC LLC, TLC S-Corp, and Pacfic Med Eval were agents of INSYS as they were utilized by Dr. Blackburn to further his tortious conduct detailed more fully below.

87.

Dr. Blackburn has been repeatedly investigated and disciplined by the Oregon medical board for, among other things, unsafe prescribing of opioid medication.

88.

Defendant James David Gallant, MD, ("Dr. Gallant") Medical License No. MD12529 was a practicing physician in the state of Oregon whose last known office address was 981 NW Spruce Ave. Corvallis, OR 97330.

89.

At all material times, Dr. Gallant acted both individually and as an actual agent or apparent agent of INSYS.

90.

Defendant Corvallis Internal Medicine, P.C ("Corvallis Med") is an Oregon

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professional corporation with its principal place of business at 5960 NW Wildview Place, Corvallis, OR 97330. Defendant Gallant Internal Medicine, P.C. ("Gallant Med") is the predecessor to Corvallis Med.

91.

On information and belief, Corvallis Med and Gallant Med were agents of INSYS as they were utilized by Dr. Gallant to further his tortious conduct detailed more fully below.

92.

Dr. Gallant has been repeatedly investigated and disciplined by the Oregon medical board for, among other things, unsafe prescribing of opioid medication. According to an order of the Oregon Medical Board, dated October 6, 2016, Gallant's medical license is retired pending investigation.

93.

Defendant Stuart Michael Rosenblum, MD, ("Dr. Rosenblum") Medical License No. MD13567 is a practicing physician in the state of Oregon whose office address is 1015 NW 22nd Avenue, Portland, OR 97210. Rosenblum is a pain medicine doctor and anesthesiologist.

94.

At all material times, Dr. Rosenblum acted both individually and as an actual agent or apparent agent of INSYS.

95.

Defendant Stuart M. Rosenblum, M.D. LLC ("Rosenblum LLC") is an Oregon limited liability corporation with its principal place of business at 1849 NW Kearney Street, Suite 102, Portland, OR 97209. Dr. Rosenblum is a member of the LLC.

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96.

On information and belief, Rosenblum LLC was an agent of INSYS as it was utilized by Dr. Rosenblum to further his tortious conduct detailed more fully below.

C. *Drug-Distributor Defendants*

97.

Defendant McKesson Corporation ("McKesson") is registered with the Oregon Secretary of State as a Delaware corporation with its principal office located in San Francisco, California, doing business as McKesson Drug Company. McKesson is the largest pharmaceutical distributor in North America. McKesson delivers approximately one-third of all pharmaceuticals used in North America. McKesson does substantial business in Oregon wherein it distributes pharmaceuticals in Multnomah County. McKesson has sustained, continuous business activity in Multnomah County, Oregon.

98.

In 2008, McKesson paid the Department of Justice $13.25 million for failing to comply with its obligations under the Controlled Substances Act. Specifically, the government alleged that McKesson failed to report suspicious orders for opioids from internet pharmacies. On January 17, 2017, the Department of Justice announced it had reached another settlement with McKesson Corporation, this time to pay $150 million to resolve allegations McKesson had violated the Controlled Substances Act by filling millions of orders for drugs, including highly addictive opioids, without sufficient anti-abuse safeguards. According to the press release "[f]rom 2008 until 2013, McKesson supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills,

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frequently misused products that are part of the current opioid epidemic."[19] The DOJ said in the release. As part of the nationwide settlement, McKesson agreed to suspend sales of controlled substances from distribution centers in Colorado, Ohio, Michigan, and Florida for multiple years, which the DOJ touted as the "most severe sanctions ever" agreed to by a Drug Enforcement Administration registered distributor.[20]

99.

McKesson has a distribution facility in Wilsonville, Oregon.

100.

Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is registered with the Oregon Secretary of State as a Delaware corporation with its principal office located in Chesterbrook, Pennsylvania. AmerisourceBergen is the second largest pharmaceutical distributor in North America. AmerisourceBergen does substantial business in the State of Oregon wherein it distributes pharmaceuticals in Multnomah County. AmerisourceBergen has sustained, continuous business activity in Multnomah County, Oregon.

101.

Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio corporation with its principal place of business in Dublin, Ohio. Cardinal is the third largest distributor of pharmaceuticals in North America. Cardinal Health, Inc. does substantial business in the State of Oregon wherein they distribute pharmaceuticals in Multnomah County.

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[19] U.S. DOJ Press Release, *McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* (Jan. 17, 2017) (*available at* https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders).

[20] *Id.*

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102.

In 2013, Cardinal paid a $34 million fine for failing to report suspicious orders of hydrocodone.[21] Cardinal's Lakeland, Florida warehouse was suspended by the DEA for two years for shipping suspect orders of opioids.

103.

Defendant Fusion Wellness Clinic is an illegitimate "pill mill" which illegally wrote prescriptions for controlled substances absent medical necessity located at 2442 SE 101st Ave., Portland, Oregon.

104.

Defendant Julie Ann Demille, ("Demille"), a nurse practitioner, owned and operated the Fusion Wellness. Fusion Wellness is registered with the Oregon Secretary of State as an assumed business name by Demille.

105.

McKesson, AmerisourceBergen, and Cardinal are collectively referred to herein as "Drug-Distributor Defendants," because they engaged in the wholesale and retail distribution of opioids.

D. ***Does 1 Through 100***

106.

The County lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100. The County will amend this Complaint to show their true names and capacities when they are ascertained. The County is informed and

[21] U.S. DOJ Press Release, *United States Reaches $34 Million Settlement With Cardinal Health For Civil Penalties Under The Controlled Substances Act* (Dec. 23, 2016) (*available at* https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under).

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believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

III. FACTUAL BACKGROUND

107.

Since 1970, opioids have been regulated as controlled substances because of their potential to cause physical dependence, addictive, and death. Research during the 1970s and 1980s confirmed the life-altering and dangerous qualities associated with opioid use. Consequently, during that time, leading authorities discouraged, and even prohibited, the use of opioid therapy for chronic pain.

108.

Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may continue for months after a complete withdrawal from opioids.

109.

When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction to which he has become accustomed—up to and including doses that are "frighteningly high."[22] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of

[22] M. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170 ARCHIVES OF INTERNAL MED. 1422 (2010).

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addiction. And, a patient can take opioids at the continuously escalating dosages and still overdose at recommended levels.

A. ***Opioid Therapy Makes Patients Sicker Without Long-Term Benefits.***

110.

The opioid pain pills manufactured by Drug-Maker Defendants vary by duration. Long-acting opioids pain pills, include: Purdue's OxyContin and MS Contin, Janssens's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian. Long-acting opioid pain pills are designed to be taken once or twice daily and purport to provide continuous therapy for 12 hours. Short-acting opioids, include: Cephalon's Actiq and Fentora. Short-acting opioids are designed to supplement long-acting opioids to address "episodic pain" and provide fast-acting therapy lasting 4 to 6 hours.

111.

In the 1990s, Drug-Maker Defendants invented and then marketed the idea that it was safe to treat chronic-pain with long-acting opioids and supplemental short-acting, rapid-onset opioids for episodic pain.

112.

There is no scientific evidence supporting the safety or efficacy of opioids for long-term use. Drug-Maker Defendants are fully aware of the lack of such scientific evidence. While promoting opioids to treat chronic pain, the Drug-Maker Defendants failed to disclose the lack of evidence to support their long-term use and have failed to disclose the substantial scientific evidence that chronic opioid therapy makes patients sicker.

113.

There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. For example, a 2007

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systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain.[23]

114.

Substantial evidence exists that opioid drugs are ineffective to treat chronic pain, and worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments.[24]

115.

Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

116.

While opioids may work in the short-term for acute pain, when used on a long term-basis, function generally declines, as does general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.[25]

117.

The foregoing is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate

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[23] Martell, *et al.*, *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, 146(2) ANN. INTERN. MED. 116-127 (Jan. 16, 2017).

[24] A. Furlan *et al.*, *Opioids for Chronic Non-Cancer Pain: A Meta-Analysis of Effectiveness and Side Effects*, 174(11) CAN. MED. ASS'N J. 1589 (2006) (this same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids); *and* K. Seal, *Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. AM. MED. ASS'N 940 (2012).

[25] *See* A. Rubenstein, *Are We Making Pain Patients Worse?*, SONOMA MEDICINE (Fall 2009).

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an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity. This is due partly to addiction and other side effects.

118.

For example, as many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment, and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.[26]

119.

Drug-Maker Defendants knew about the medical problems associated with long-term use of opioids but chose not to change their marketing strategies and actively promoted the long-term use of opioids.

120.

In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the "grave risks" of opioids, including "addiction, overdose, and even death."[27] The FDA further warned, "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression,

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[26] *See* National Headache Foundation, *Opioid Treatment of Migraine Is Associated with Multiple Risks* (June 15, 2012) (*available at* http://www.headaches.org/2012/06/15/opioid-treatment-of-migraine-is-associated-with-multiple-risks/); *see also,* National Headache Foundation, *Opioids and Barbiturates Still Prescribed too Often for Headache, Migraine*, (Dec. 16, 2015) (*available at http://www.headaches.org/2015/12/16/opioids-and-barbiturates-prescribed-too-often-for-migraine-headache/*).

[27] Press Release, *FDA Announces Enhanced Warnings for Immediate-Release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death* (Mar. 22, 2016) (available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm).

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coma, and death."[28] Because of those grave risks, the FDA said that long-acting or extended release opioids "should be used only when alternative treatments are inadequate."[29] The FDA required that, going forward, opioid makers of long-acting formulations clearly communicate these risks in their labels.

121.

In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release opioid pain medications as it had for extended release opioids in 2013.[30] The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.[31]

122.

The facts, which the FDA relied on in 2013 and 2016, were well known to the Drug-Maker Defendants in the 1990s when their deceptive marketing began. However, Drug-Maker Defendants knowingly and intentionally suppressed and concealed these facts.

B. ***Drug-Maker Defendants' Lied to Upend Accurate Scientific and Medical Understanding About the Dangers of Opioids.***

123.

Before Drug-Maker Defendants began their comprehensive campaign of lies and deceptions, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, like pain immediately after surgery, or for cancer or palliative care. In those instances, the risks of addiction are low or of little significance.

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[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] *Id.*

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124.

The market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief. Drug-Maker Defendants understood that if they could sell opioids for long-term chronic pain relief, they could achieve increased levels of sales and substantial profits because they would have a large market of consumers. Additionally, Drug-Maker Defendants understood that physical dependence and addiction would greatly increase the likelihood that those new costumers would come back indefinitely.

125.

To increase their profits, Drug-Maker Defendants knew that they would need to convince doctors and patients that long-term opioid therapy was safe and effective even though all available scientific evidence showed that long-term opioid therapy was not safe. Meaning, Drug-Maker Defendants needed to persuade physicians to ignore scientific facts, abandon long-held apprehensions about prescribing opioids, and instead prescribe opioids for durations previously understood to be unsafe.

126.

Drug-Maker Defendants knew that their goal of increasing profits by promoting the prescription of opioids for treatment of chronic-pain would lead directly to increases in health care costs for patients, insurers, and payors, as well as increased costs to governmental entities like Multnomah County who are obligated to provide services to promote public health and safety.

127.

Drug-Maker Defendants developed and executed a common strategy to reverse the long-settled understanding of the relative risks and benefits of chronic opioid therapy. Rather than add to the collective body of medical knowledge concerning the best ways to treat pain

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and improve patient quality of life, Drug-Maker Defendants instead sought to distort medical and public perception of existing scientific data.

128.

Drug-Maker Defendants, collectively and individually, poured vast sums of money into marketing, advertising, generating articles, continuing medical education courses ("CMEs"), and other "educational" materials, conducting sales visits to individual doctors, and supporting a network of professional societies and advocacy groups which was intended to, and which did, create a new, yet false, consensus supporting the long-term use of opioids.

129.

To convince doctors and patients that opioids are safe, Drug-Maker Defendants deliberately trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. Succinctly, those misrepresentations are as follows:

(a) Starting patients on opioids is low-risk because most patients will not become addicted.

(b) Patients who are at risk of addiction could be easily identified and managed.

(c) Patients who displayed signs of addiction probably are not addicted and, in any event, could easily be weaned from the drugs.

(d) The use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, does not pose special risks.

(e) Abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive.

130.

These misrepresentations are dishonestly designed to reinforced and verify each other

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without need for outside reference or examination. This closed loop of pseudo-scientific reasoning created a dangerous and inhumane environment wherein opioids were falsely deemed safe for long-term use, even in high doses, and clear signs of addiction were ignored as so-called pseudoaddiction.

131.

Defendants have not only failed to correct these misrepresentations, they continue to make them today.

C. *Drug-Maker Defendants' Campaign of Lies and Deceptions Is Comprehensive.*

132.

Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Drug-Maker Defendants' messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising in each sales territory. Drug-Maker Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

133.

Drug-Maker Defendants ensure marketing consistency nationwide through:

(a) National and regional sales representative training

(b) National training of local medical liaisons, the company employees who respond to physician inquiries

(c) Centralized speaker training

(d) Single sets of visual aids, speaker slide decks, and sales training materials

(e) Nationally coordinated advertising

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134.

Drug-Maker Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

135.

Consequently, Drug-Maker Defendants employed the same marketing plans and strategies and deployed the same messages in Oregon as they did nationwide.

136.

As a part of their marketing scheme, Drug-Maker Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including Oregon. For example, Drug-Maker Defendants focused their untrue marketing representations on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Drug-Maker Defendants' misrepresentations.

137.

Drug-Maker Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Drug-Maker Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are

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more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

138.

Drug-Maker Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Drug-Maker Defendants of this, and Drug-Maker Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Drug-Maker Defendants' misrepresentations, and Endo and Purdue have recently entered into agreements prohibiting them from making some of the same misrepresentations described in this Complaint in the State of New York.

139.

Drug-Maker Defendants deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told

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opioids were potentially addictive.[32]

140.

Drug-Maker Defendants' deliberate marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective.

141.

Drug-Maker Defendants' deliberate and dangerous marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Drug-Maker Defendants' spending on their deceptive marketing scheme. Drug-Maker Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million. The escalating number of opioid prescriptions written by doctors who were deceived by Drug-Maker Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Oregon.

142.

In August 2016, then-U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive

[32] Press Release, *Missed Questions, Missed Opportunities*, Hazelden Betty Ford Foundation (Jan. 27, 2016) (*available at* http://www.hazeldenbettyford.org/about-us/news-media/press-release/2016-doctors-missing-questions-that-could-prevent-opioid-addiction).

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when prescribed for legitimate pain."[33]

143.

Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses."[34] Patients receiving prescription opioids for chronic pain account for most overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[35]

144.

Contrary to Drug-Maker Defendants' misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Drug-Maker Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet.[36] Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

145.

Drug-Maker Defendants knew and should have known about these harms that their

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[33] Murthy, U.S. Surgeon General, *Letter to All Physicians*, (Aug. 2016) (*available at* http://i2.cdn.turner.com/cnn/2016/images/08/25/sg.opioid.letter.pdf).
[34] CDC Report, *Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014*, Morbidity and Mortality Weekly Report (Jan. 1, 2016) (*available at* https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm).
[35] *Id.*
[36] U.S. Dep't of Health & Human Servs., *2011 National Survey on Drug Use and Health* (Sept. 2012).

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unscrupulous marketing has caused. Drug-Maker Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Drug-Maker Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew—and, indeed, intended—that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain. Therefore, Drug-Maker Defendants' causal role is not broken by the involvement of doctors.

146.

Drug-Maker Defendants' actions are not permitted nor excused by the fact that their drug labels (with the exception of the Actiq/Fentora labels) may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Drug-Maker Defendants license to misrepresent the risks and benefits of opioids.

147.

Drug-Maker Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Drug-Maker Defendants also could harness and hijack what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' pain. The result has been untold suffering by the targets of Drug-Maker Defendants' marketing scheme and the greatly diminished health and safety of countless communities including Multnomah County.

148.

While the use of opioids has taken an enormous toll on Multnomah County and its residents, Drug-Maker Defendants have realized blockbuster profits. In 2014 alone, opioids

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generated $11 billion in revenue for drug companies like Drug-Maker Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from advertising endeavors and other unlawful and unfair conduct described above.

D. ***Drug-Maker Defendants Used "Unbranded" Marketing to Avoid Oversight and Detection.***

149.

Drug companies' promotional activity can be "branded" or "unbranded." "Unbranded" promotional activity refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can evade the extensive regulatory framework governing branded communications.

150.

A drug company's branded marketing, which identifies and promotes a specific drug, must:

(a) be consistent with its label and supported by substantial scientific evidence;

(b) not include false or misleading statements or material omissions; and

(c) fairly balance the drug's benefits and risks.

151.

The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to assess accurately the risks and benefits of drugs for their patients.

152.

Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") places further restrictions on branded marketing. It prohibits the sale in interstate commerce of drugs that

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are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular." "Labeling" includes more than the drug's physical label; it also includes "all * * * other written, printed, or graphic matter * * * accompanying" the drug, including promotional material. The term "accompanying" is interpreted broadly to include promotional materials—posters, websites, brochures, books, etc.—disseminated by or on behalf of the manufacturer of the drug. Thus, Drug-Maker Defendants' promotional materials are part of their drugs' labels and required to be accurate, balanced, and not misleading.

153.

Branded promotional materials for prescription drugs must be submitted to the FDA when they are first used or disseminated. If, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

154.

Drug-Maker Defendants avoided using branded advertisements to spread their deceptive messages and claims regarding opioids. They did so to evade regulatory review.

155.

Instead, Drug-Maker Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unregulated unbranded marketing materials—materials that generally promoted opioid use but did not name a specific opioid while doing so. Through these unbranded materials, Drug-Maker Defendants presented information and instructions concerning opioids generally that were false and misleading.

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156.

By acting through third-parties, Drug-Maker Defendants gave the false appearance that their messages reflected the views of independent third parties. Later, Drug-Maker Defendants would cite to these sources as "independent" corroboration of their own statements. Further, as one physician adviser to Drug-Maker Defendants noted, third-party documents had not only greater credibility, but also broader distribution, as doctors did not "push back" at having materials, for example, from the non-profit American Pain Foundation ("APF") on display in their offices, as they would with drug company pieces.

157.

As part of their marketing scheme, the Drug-Maker Defendants spread and validated their deceptive messages through the following unbranded methods of deception:

(a) So-called "key opinion leaders" (i.e., physicians who influence their peers' medical practice, including but not limited to prescribing behavior) ("KOLs"), who wrote favorable journal articles and delivered supportive CMEs

(b) A body of biased and unsupported scientific literature

(c) Treatment guidelines

(d) Continuing Medical Education ("CMEs") courses

(e) Unbranded patient education materials disseminated through groups purporting to be patient-advocacy and professional organizations ("Front Groups"), which exercised their influence both directly and indirectly through Drug-Maker Defendant-controlled KOLs who served in leadership roles in these organizations

158.

Drug-Maker Defendants disseminated many of their false, misleading, and

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unsupported messages through the above methods of deception because they appeared to uninformed observers to be independent. Through unbranded materials, Drug-Maker Defendants presented information and instructions concerning opioids to the marketplace generally that were intentionally false and misleading, and upon which the marketplace had the right to rely and did rely on such false and misleading information which proximately caused injury and damages to the entire marketplace and more particularly to Multnomah County.

159.

Even where such unbranded messages were disseminated through third-parties, Drug-Maker Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete.

160.

Drug-Maker Defendants' sales representatives distributed third-party marketing materials.

161.

Drug-Maker Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by third-parties, ensuring that they were consistently in control of their content. By funding, directing, editing, and distributing these materials, Drug-Maker Defendants exercised control over their deceptive messages and acted in concert with these third-parties fraudulently to promote the use of opioids for the treatment of chronic pain.

162.

The unbranded marketing materials that the Drug-Maker Defendants assisted in

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creating and distributing either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied or minimized those risks.

163.

Drug-Maker Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	**Opana ER Advertisement (Branded)**
"People who take opioids **as prescribed usually do not become addicted**."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

164.

Drug-Maker Defendants' claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

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165.

The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

166.

At all times relevant to this Complaint, Drug-Maker Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Drug-Maker Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Drug-Maker Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Drug-Maker Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

167.

Drug-Maker Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Drug-Maker Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Drug-Maker Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

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168.

Finally, Drug-Maker Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Drug-Maker Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Drug-Maker Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by Multnomah County.

169.

Thus, Drug-Maker Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that Multnomah County now asserts. Multnomah did not know of the existence or scope of Drug-Maker Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

1. *Drug-Maker Defendants Spread Lies Through Advertising.*

170.

Drug-Maker Defendants' engaged in direct marketing of opioids to doctors and patients through advertising.

171.

Each Drug-Maker Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, Drug-Maker Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

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2. *Drug-Maker Defendants' Spread Lies Through In-Person Marketing.*

172.

Each Drug-Maker Defendant promoted and continues to promote the use of opioids for chronic pain through "detailers"—sales representatives who visited individual doctors and medical staff in their offices. Drug-Maker Defendants have not corrected this misinformation. Instead, each Drug-Maker Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Drug-Maker Defendants spent $168 million on detailing branded opioids to doctors. This amount is twice as much as Drug-Maker Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis.

173.

Drug-Maker Defendants' detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that between June 2009 and February 2010, Actavis sales representatives distributed promotional materials that omitted and minimized serious risks associated with Kadian, including the risk of misuse, abuse, and diversion of opioids and, specifically, the risk that opioids have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion.

174.

Drug-Maker Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, Drug-Maker Defendants purchase, manipulate and

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analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, Drug-Maker Defendants know their detailing to doctors is effective.

3. *Drug-Maker Defendants Spread Lies Through Speaker Programs.*

175.

Drug-Maker Defendants conduct speaker programs to communicate their messages. In so doing, Drug-Maker Defendants identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Drug-Maker Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Drug-Maker Defendants.

a. Drug-Maker Defendants doctor-to-doctor deception in Oregon.

176.

INSYS paid Dr. Blackburn, Dr. Gallant, and Dr. Rosenblum to unsafely prescribe INSYS's opioid pain killer Subsys and to persuade other physicians to do the same.

177.

Subsys is the powerful and highly-addictive narcotic fentanyl in spray form. Subsys is sprayed under a patient's tongue and is absorbed rapidly into the bloodstream. Subsys is one of a class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

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178.

The FDA determined that Subsys may only be lawfully promoted "for management of breakthrough pain in cancer patients 18 years of age or older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[37] The FDA also determined that Subsys should only be prescribed by "pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."[38]

179.

The first TIRF drug approved by the FDA was Actiq and it has the same approved indications as Subsys. In 2008, Cephalon plead guilty to criminal and civil charges that it promoted Actiq for off-label uses and targeted physician specialists, like physiatrists, who do not usually treat cancer patients but commonly treat neck and back pain. Additionally, Cephalon admitted to promoting Actiq off-label to treat migrane headaches. Because of this action, even before Subsys was approved for sale, INSYS knew that off-label use of TIRF drugs and marketing to physiatrists was wrong and carried with it the potential for civil and criminal penalties.

180.

Additionally, the FDA instituted a Risk Evaluation and Management Strategy ("REMS") for Subsys and other fentanyl products, "[t]his REMS, called the TIRF REMS Access program, consists of a restricted distribution program to reduce the risk of misuse, abuse, addiction, and overdose with TIRF medicines."[39]

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[37] FDA Subsys Warning Label (*available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202788s000lbl.pdf).
[38] *Id.*
[39] *Questions and Answers: FDA approves a class Risk Evaluation and Mitigation Strategy (REMS) for transmucosal immediate-release fentanyl (TIRF) medicines* (Dec. 28, 2011) (*available at* https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm284717.htm#Q3).

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181.

Instead of educating prescribers and the public about the appropriate use of Subsys, INSYS promoted Subsys for off-label uses like neck and back pain and targeted physiatrists and other doctors that rarely treat cancer patients. In fact, INSYS targeted doctors who already prescribed Actiq and other TIRFs because they had already been exposed to Cephalon's unlawful off-label promotional campaign.

182.

To reach their target doctors, INSYS paid Dr. Gallant and Dr. Rosenblum to promote Subsys to other doctors.

183.

Dr. Gallant is not board certified and is not a pain specialist. Nonetheless, INSYS hired Dr. Gallant as its top Oregon doctor to train other doctors about the safe use of Subsys.

184.

INSYS paid Dr. Gallant up to $2,400 per talk to give short promotional talks about Subsys to other doctors.

185.

On at least 3 separate occasions, INSYS paid Dr. Rosenblum $1,600 to meet with doctors in social settings to promote Subsys. These meetings took place in restaurants where INSYS paid for all the food, drinks, and entertainment.

186.

Dr. Gallant and Dr. Rosenblum acted as agents of INSYS in promoting Subsys to other doctors and as co-conspirators in the broader civil conspiracy that is the basis of this civil action.

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187.

On October 23, 2012, INSYS paid Dr. Gallant $2,400 to speak to Dr. Blackburn and one of his employees at a catered lunch at Blackburn's office. INSYS paid Dr. Rosenblum to give the same talk to Dr. Blackburn and two other doctors at a restaurant in Eugene.

188.

In 2013, Dr. Gallant and Dr. Rosenblum were responsible for approximately 80% of all Subsys prescriptions filled in Oregon. For the years 2012 and 2013, Gallant, Rosenblum, and Blackburn were responsible for 78% of all Oregon Subsys prescriptions.

189.

On information and belief, INSYS paid kickbacks to Dr. Gallant, Dr. Rosenblum, and Dr. Blackburn as compensation for their prolific prescribing of Subsys. Among other things, these kickbacks were paid in the form of sham speakers fees.

190.

These kickbacks transformed these doctors from caretakers of their patients into agents of INSYS in effect directly marketing Subsys to their patients on INSYS's behalf and being compensated to do so.

191.

Drug-Maker Defendants' aggressive marketing and sales techniques directed at and directly involving doctors is not unique to INSYS. The full extent of Drug-Maker Defendants' doctor-to-doctor deception, in Oregon, is not fully known. On information and belief, each Drug-Maker Defendants had and have doctors in Oregon working to promote their opioid pain killers. Plaintiff has pled Doe Defendants with the intent to add additional

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doctor defendants as they become known.

4. *Drug-Maker Defendants Spread Lies Through Key Opinion Leaders.*

192.

Drug-Maker Defendants cultivated a select circle of doctors who were chosen and sponsored by Drug-Maker Defendants solely because they favored the aggressive treatment of chronic pain with opioids. Pro-opioid doctors have been at the center of Drug-Maker Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. These pro-opioid doctors have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of opioid therapy for chronic pain. They have served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Drug-Maker Defendants could exert control of each of these modalities through their KOLs.

193.

In return for their pro-opioid advocacy, Drug-Maker Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish.

194.

Drug-Maker Defendants cited and promoted their KOLs and studies or articles by their KOLs to broaden the chronic opioid therapy market. By contrast, Drug-Maker Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy.

195.

Drug-Maker Defendants carefully vetted their KOLs to ensure that they were likely to

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remain on-message and supportive of their agenda. Drug-Maker Defendants also kept close tabs on the content of the materials published by their KOLs.

196.

In their promotion of the use of opioids to treat chronic pam, Drug-Maker Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and Drug-Maker Defendants.

197.

Nationally, two KOLs were most prolific and most pervasive in their spread of Drug-Maker Defendants Lies.

a. ***Prolific KOL Russell Portenoy, M.D.***

198.

Russell Portenoy, M.D., former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

199.

Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Defendants.

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200.

Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast in Oregon and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[40]

201.

Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist." Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[41]

b. ***Prolific KOL Lynn Webster, MD***

202.

Another KOL, Lynn Webster, MD, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr.

[40] Good Morning America television broadcast, ABC News (Aug. 30, 2010).
[41] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., (Dec. 17, 2012.)

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Webster was President in 2013, and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Drug-Maker Defendants (including nearly $2 million from Cephalon).

203.

During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Purdue, Janssen and Endo.[42]

204.

In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, Managing Patient's Opioid Use: Balancing the Need and the Risk. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and

[42] *See Opioid Risk Tool* (*available at* https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf).

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was intended to reach Oregon doctors.

205.

Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and his co-author wrote in a book entitled Avoiding Opioid Abuse While Managing Pain (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."

5. ***Drug-Maker Defendants Spread Lies Through Scientific Literature.***

206.

Rather than promote safety and efficacy testing of opioids for long-term use, Drug-Maker Defendants led physicians, patients, and health care payors to believe that such tests had already been done when none had occurred. Drug-Maker Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that understated the risks and overstated the benefits of long-term use, appeared to be the result of independent, objective research, to shape the perceptions of prescribers, patients, and payors. This literature was, in fact, marketing material which Drug-Maker Defendants used to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

207.

To accomplish their goal, Drug-Maker Defendants—sometimes through third-party

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consultants and/or front groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

208.

Drug-Maker Defendants' plans for these materials did not originate in the departments within Drug-Maker Defendants' organizations that are responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients. Rather, they originated in Drug-Maker Defendants marketing departments and with Drug-Maker Defendants' marketing and public relations consultants.

209.

In these materials, Drug-Maker Defendants (or their surrogates) often claimed to rely on "data on file" or presented posters, neither of which are subject to peer review. Still, Drug-Maker Defendants presented these materials to the medical community as scientific articles or studies, even though the Drug-Maker Defendants' materials were not based on reliable data and subject to the scrutiny of others who are experts in the same field.

210.

Drug-Maker Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even when they knew that the articles distorted the significance or meaning of the underlying study.

211.

Drug-Maker Defendants worked not only to create and promote favorable studies in the literature, but to discredit or suppress negative information. Drug-Maker Defendants' studies and articles often targeted articles that contradicted their claims or raised concerns about chronic opioid therapy. To do so, the Drug-Maker Defendants—often with the help of third-party consultants—used a broad range of media to get their message out, including

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negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

6. *Drug-Maker Defendants Spread Lies Through Front Groups*

212.

Drug-Maker Defendants' strategy—to plant and promote supportive literature and then to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted those claims-was flatly inconsistent with their legal obligations. The strategy was intended to, and did, distort prescribing patterns by distorting the truth regarding the risks and benefits of opioids for chronic pain relief.

213.

Drug-Maker Defendants also entered arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Drug-Maker Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Drug-Maker Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Drug-Maker Defendants.

214.

These Front Groups depended on Drug-Maker Defendants for funding and, in some cases, for survival. Drug-Maker Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In so doing, Drug-Maker Defendants made sure that the Front Groups would generate only the messages Drug-Maker Defendants wanted delivered.

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Despite this, the Front Groups held themselves out as independent and serving the needs of their members—either patients suffering from pain or doctors treating those patients.

215.

Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. American Pain Foundation ("APF") was the most prominent. But there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

a. APF—Drug-Maker Defendants' Most Prominent Front Group.

216.

The most prominent of Drug-Maker Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding. Purdue provided $1.7 million.

217.

APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All the programs and materials were available nationally and were intended to reach Oregonians.

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218.

APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Drug-Maker Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. APF functioned largely as an advocate for the interests of Drug-Maker Defendants, not patients. Indeed, as early as 2001, Purdue made clear its goal in funding APF was to strategically align its investments in nonprofit organizations that share its business interests.

219.

APF's clear lack of independence—in its finances, management, and mission—and its willingness to allow Drug-Maker Defendants to control its activities and messages support an inference that each Drug-Maker Defendant that worked with it could exercise editorial control over its publications.

220.

Indeed, the U.S. Senate Finance Committee began investigating APF in May 2012, to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Drug-Maker Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization due to irreparable economic circumstances. APF "cease[d] to exist, effective immediately."[43]

[43] *See*, Ornstein, Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012) (*available at* https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups).

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b. Front Groups Issue False Pain Guidelines.

221.

The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Drug-Maker Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Drug-Maker Defendants' deceptive marketing of chronic opioid therapy.

222.

AAPM received over $2.2 million in funding from opioid manufacturers since 2009. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

223.

AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another

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past AAPM president, Dr. Scott Fishman, stated that he would place the organization at the forefront of teaching that the risks of addiction are small and can be managed.

224.

AAPM's staff understood they and their industry funders were engaged in a common task. Drug-Maker Defendants could influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

225.

In addition, treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Drug-Maker Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Drug-Maker Defendants' discussed treatment guidelines with doctors during individual sales visits.

226.

In 1997, AAPM and the American Pain Society jointly issued a consensus statement, The *Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.

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227.

AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

228.

The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Oregon during the relevant time period, are still available online, and were reprinted in the Journal of Pain. Drug-Maker Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

229.

Drug-Maker Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Drug-Maker Defendants combined their efforts through the Pain Care Forum (PCF), which

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began in 2004, as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Drug-Maker Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which Drug-Maker Defendants determined would reduce prescribing.

E. ***Drug-Maker Defendants Lie About the Benefits of Opioids.***

230.

Drug-Maker Defendants grossly overstated the benefits of opioid therapy for chronic pain.

231.

To convince doctors and patients that opioids should be used to treat chronic pain, Drug-Maker Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Drug-Maker Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Drug-Maker Defendants failed to correct

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these false and deceptive claims, they continue to make them today.

232.

For example, Drug-Maker Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples are:

(a) Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

(b) Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

(c) Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

(d) Responsible Opioid Prescribing (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

(e) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online

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until APF shut its doors in 2012.

(f) Endo's NIPC website painknowledge.com claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

(g) Endo was the sole sponsor, through NIPC, of a series of CMEs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

(h) Janssen sponsored, funded, and edited a website, Let's Talk Pain, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube.

(i) Purdue sponsored the development and distribution of APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health- related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011, and is still available online today.

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233.

Drug-Maker Defendants' sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

234.

These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely."[44] The CDC reinforced this conclusion throughout its 2016 Guideline: "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later * * *."[45] "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."[46] "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[47]

235.

The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

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[44] Dowell, MD, *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, Morbidity and Mortality Weekly Report (Mar. 18, 2016) (*available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

[45] *Id.*

[46] *Id.*

[47] *Id.*

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236.

The 2016 CDC Guideline was not the first time a federal agency repudiated Drug-Maker Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

237.

Drug-Maker Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Drug-Maker Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. For example:

(a) Actavis's predecessor created a patient brochure for Kadian in 2007 that stated: "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis

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continued to use these materials in 2009 and beyond.

(b) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.

(c) Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

(d) Endo distributed a pamphlet edited by a KOL entitled Understanding Your Pain: Taking Oral Opioid Analgesics, which was available during the time period of this Complaint on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased * * * You won't 'run out' of pain relief."

(e) Janssen sponsored a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

(f) Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

(g) Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which taught that dosage escalations are "sometimes

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necessary," even unlimited ones, but did not disclose the risks from high opioid dosages.

(h) Purdue sponsored a CME entitled Overview of Management Options that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

(i) Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,"[48] challenging the correlation between opioid dosage and overdose.

238.

Drug-Maker Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Drug-Maker Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013, and IR opioids in 2016, to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

239.

In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours—a fact that Purdue has known at all times relevant to this action.

[48] www.cpdd.org.

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According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

240.

Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continue to tell Oregon doctors that OxyContin lasts a full 12 hours.

241.

Drug-Maker Defendants also engaged in other unlawful, unfair, and fraudulent misconduct. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid- tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the

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potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

242.

Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example: Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.[49] The CME is still available online.

243.

Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

244.

In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal

[49] *See* http://www.medscape.org/viewarticle/775451_3.

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Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain"– and not just cancer pain.

245.

Cephalon's aggressive and deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

246.

Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and

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safety.

247.

The State of New York's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

248.

Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing, paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing, and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

F. ***Through Their Lies, Drug-Maker Defendants Target Addicts and Potential Addicts.***

249.

Through their deception, Drug-Maker Defendants insidiously target patients who were most likely to become addicted. And then crafted a strategy to obfuscate the fact of addiction from treating doctors. The best-case scenario: unwitting doctors facilitate the maintenance and progression of patients' opioid addiction. The worst-case scenario: unscrupulous doctors prey upon addict patients. The opioid epidemic has seen both scenarios play out repeatedly.

1. ***Drug-Maker Defendants Lie About Addicts.***

250.

Drug-Maker Defendants falsely instructed doctors and patients that addiction risk

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screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. In so-doing, Drug-Maker Defendants in effect directly marketed their products to those most susceptible to addiction and its life-shattering consequences.

251.

These misrepresentations were especially insidious because Drug-Maker Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Drug-Maker Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain.

252.

Among other things, Drug-Manufacturer Defendants spread these lies in the following ways:

(a) In 2007, Endo paid for a supplement in the Journal of Family Practice that emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

(b) In 2011, Purdue sponsored that claimed screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

(c) As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

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253.

The 2016 CDC Guideline confirms the falsity of these misrepresentations. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse—for improving outcomes related to overdose, addiction, abuse, or misuse. As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for opioid abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

2. *Drug-Maker Defendants Lie About Addiction.*

254.

Drug-Maker Defendants falsely instructed doctors and patients that the signs of addiction are in-fact signs of undertreated pain and should be treated by prescribing more opioids. Manufacturer Defendants called this phenomenon "pseudoaddiction" and falsely claimed that "pseudoaddiction" is substantiated by scientific evidence.

255.

Among other things, Drug-Manufacturer Defendants spread these lies in the following ways:

(a) Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which teaches that drug seeking behaviors like "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction," rather than true addiction. *Responsible Opioid Prescribing* remains for sale online. The 2012 edition, which also remains available online, continues to teach that

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"pseudoaddiction" is real.

(b) Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction * * * refers to patient behaviors that may occur when pain is under-treated * * *. Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

(c) In 2009, Endo sponsored a CME program which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain and distributed that program through a front group substantially controlled and funded by it.

(d) In 2011, Purdue published a pamphlet which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

(e) Purdue sponsored a CME program entitled Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long- acting opioid.

256.

The 2016 CDC Guideline rejects the concept of "pseudoaddiction." The Guideline

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nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment * * * are unlikely to experience pain relief with longer- term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[50]

257.

In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the State of New York, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'"[51] Consistent with this, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing."[52]

3. *Drug-Maker Defendants Lie About Abuse Deterrent Products.*

258.

Drug-Maker Defendants' deceptively marketed so-called abuse-deterrent properties of some of their opioids and have thereby created a false impression that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

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[50] Dowell, MD, *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, Morbidity and Mortality Weekly Report (Mar. 18, 2016) (*available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

[51] In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. Assurance No.: 15-228 (*available at* https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf).

[52] *Id.*

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259.

More specifically, Drug-Maker Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse." Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

260.

In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."

261.

These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Drug-Maker Defendants successfully convinced doctors and patients to discount those risks—with the direst consequences suffered by those most susceptible to addiction.

G. *Drug-Distributor Defendants' Filled and Continue to Fill Suspicious Orders.*

262.

The Defendants identified as Drug-Distributor Defendants are all in the business of

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pharmaceutical distribution—either as wholesale distributors or retail prescribers. Drug-Distributor Defendants as well as the Drug-Maker Defendants knew or should have known that Oregon had an exceedingly high rate of illegal use and diversion of prescription opioids.

263.

The Drug-Distributor Defendants as well as the Drug-Manufacturer Defendants knew or should have known that their activities were subject to regulations which created restrictions on the manufacture and distribution of controlled substances.

264.

The main objectives of such regulations are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Such regulations are particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Drug-Distributor Defendants are subject to a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in an authorized manner. All drugs such as the controlled substances at issue in this case are classified into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. These are subject to strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.

265.

There has been established a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market. Any entity that seeks to become involved in the

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production or chain of distribution of controlled substances must first register with the DEA.

266.

The Controlled Substances Act provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal.

267.

Distributors of Schedule II drugs—controlled substances with a "high potential for abuse," must maintain effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels. In addition, distributors that supply controlled substances to pharmacies must "design and operate a system to disclose to the [distributor] suspicious orders of controlled substances" and, in turn, disclose those suspicious orders to the regulating entity. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

268.

These regulations are designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs. Such a closed system is intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.

269.

Drug-Distributor Defendants are "one of the key components of the distribution chain. If the closed system is to function properly as intended, Drug-Distributors must be

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vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as the illegal distribution of controlled substances has a substantial and detrimental effect on the health, safety and general welfare of the American people.

270.

"Suspicious orders" include orders of an unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

271.

The closed system is specifically designed with checks and balances between registrants to ensure that controlled substances are not diverted from this closed system. The goal of this closed system, through appropriate regulation of the manufacture and distribution of drugs, is to reduce the availability of drugs subject to abuse except through legitimate channels of trade and for legitimate uses.

272.

Different entities supervise the discrete links in the chain that separate a consumer

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from a controlled substance. Strict rules and regulations carefully define each participant's role and responsibilities.

273.

Such rules and regulations require that Drug-Distributor Defendants maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

274.

The Drug-Distributor Defendants are required to design and operate a system to disclose to the registrant suspicious orders of controlled substances. The Drug-Distributor Defendants are required to inform the appropriate authorities in his area of suspicious orders when discovered. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

275.

Federal law requires that Drug-Distributor Defendants comply with applicable State and local law.

276.

Strict rules and regulations require that Drug-Distributor Defendants provide effective controls and procedures to guard against theft and diversion of controlled substances.

277.

Oregon state law requires that Drug-Distributor Defendants design and operate a system that informs the drug-distributor of suspicious orders of controlled substances and inform the Oregon Board of Pharmacy of suspicious orders when discovered. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

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278.

Drug-Distributor Defendants are required to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels.

279.

These requirements are well known to the Drug-Distributor Defendants. These regulations that have been in place for more than 40 years require distributors to report suspicious orders of controlled substances to appropriate law enforcement authority based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."

280.

The DEA sent a letter to each of the Drug-Distributor Defendants on September 26, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

281.

The DEA sent a second letter to each of the Drug-Distributor Defendants on December 27, 2007. This letter reminds the Drug-Distributor Defendants of their statutory and regulatory obligations to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The letter further explains:

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The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the pattern throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect to suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective

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controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[53]

282.

Finally, the DEA letter references the final order issued in *Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007) which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."

283.

Drug-Distributor Defendants "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[54] The preservation of the health and safety of the people is the presumed purpose behind state legislation concerning restrictions on the use of dangerous drugs.

284.

Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise

[53] DEA Letter dated December 27, 2007 sent to every entity in the U.S. registered with the DEA to manufacture or distribute controlled substances.

[54] Brief for HDMA and NACDS, *4, *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, and Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, 2012 WL 1637016, *2 (C.A.D.C.) (May 9, 2012).

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characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.

285.

Each of the Drug-Distributor Defendants is registered with the DEA as distributors in the chain of distribution of Schedule II controlled substances and has assumed the duties imposed under the CSA and state and local laws.

286.

Each of the Drug-Distributor Defendants is a "registrant" as a distributor in the chain of distribution of Schedule II controlled substances and assumed the security requirement duties imposed under the regulations adopted by the Oregon State Board of Pharmacy.

287.

Based upon information and belief, each of the Drug-Distributor Defendants sold prescription opiates, including hydrocodone and/or oxycodone, to retailers in Multnomah County, Oregon. Drug-Distributor Defendants have shipped millions of doses of highly addictive controlled pain killers into Multnomah County, many of which should have been stopped and/or investigated as suspicious orders. The sheer volume of highly addictive opioid pain medications Drug-Distributor Defendants shipped to Multnomah County was suspicious on its face. When the population of the county is taken into consideration, Drug-Distributor Defendants delivered an excessive and unreasonable number of highly addictive controlled substances into Multnomah County.

288.

Upon information and belief, Drug-Distributor Defendants knowingly filled, and

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failed to report, suspicious orders in Multnomah County. Drug-Distributor Defendants knew or should have known the amount of Oxycodone and Hydrocodone they suppled to retail pharmacies and other outlets in Multnomah County was in excess of any amount reasonable to serve a community the size of Multnomah County.

289.

Drug-Distributor Defendants owe a duty to investigate and monitor suspicious orders of prescription opiates originating from Multnomah County, Oregon. Drug-Distributor Defendants knew or should have known that they were supplying opioid medications far in excess of the legitimate needs for Multnomah County. Drug-Distributor Defendants knew or should have known that there was a high likelihood that a substantial number of the prescription pain killers they supplied to pharmacies and drug stores in Multnomah County were being diverted to illegal use or abuse.

290.

Drug-Distributor Defendants are required by law to refuse suspicious orders of prescription opiates originating from Multnomah County, Oregon.

291.

Drug-Distributor Defendants are required by law to report suspicious orders of prescription opiates originating from Multnomah County, Oregon.

292.

Drug-Distributor Defendants are required by law to prevent the diversion of prescription opiates into illicit markets in Multnomah County, Oregon.

293.

The foreseeable harm resulting from failure to adhere to the applicable law is the diversion of prescription opiates for nonmedical purposes is abuse, addiction, morbidity and

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mortality in Multnomah County, Oregon and the damages caused thereby.

294.

Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system created by the CSA collapses.

295.

Drug-Distributor Defendants are required under the CSA to maintain, on a current basis, a complete and accurate record of each prescription opioid received, sold, delivered, or otherwise disposed of.

296.

Drug-Distributor Defendants report the sale of all prescription opiates, including those to pharmacies in Multnomah County and throughout the State of Oregon, to the Automation of Reports and Consolidated Orders System (ARCOS) database.

297.

On information and belief, Multnomah County alleges that the Drug-Distributor Defendants failed to account for and accurately report sales of opioids in Multnomah County, Oregon during the relevant time.

298.

The sheer volume of prescription opioids distributed to pharmacies in Multnomah County is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.

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299.

Plaintiff is of the information and belief that the Drug-Distributor Defendants failed to report "suspicious orders" originating from Multnomah County to the DEA and to the Oregon Board of Pharmacy as required at all times relevant to this lawsuit

300.

Plaintiff alleges that the Drug-Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Multnomah County.

301.

Drug-Distributor Defendants failed to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

302.

Drug-Distributor Defendants failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the DEA of "suspicious orders when discovered."

303.

Drug-Distributor Defendants failed to provide effective controls and procedures to guard against theft and diversion of controlled substances.

304.

Drug-Distributor Defendants failed to "design and operate a system requiring reporting to the Oregon Board of Pharmacy of suspicious orders when discovered."

305.

Drug-Distributor Defendants' failed to follow these public safety statutes which would have prevented the public nuisance now suffered by Multnomah County.

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306.

Upon information and belief, Drug-Distributor Defendants failed to adopt or implement effective affirmative efforts to prevent diversion of their medicines for illegal or abusive purposes. Drug-Distributor Defendants undertook no discernible efforts to determine whether the volume of prescription pain killers it was shipping to Multnomah County was excessive and whether any of the orders it filled qualified as suspicious orders, which should have been refused. Drug-Distributor Defendants failed in their obligation to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Multnomah County, Oregon.

307.

As a result of the decade-long refusal by the Drug-Distributor Defendants to abide the law, the DEA has repeatedly taken administrative action to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 177 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. *The Drug Enforcement Administration's Adjudication of Registrant Actions*, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003 (May 2014). The public record reveals many of these actions:

(a) On April 24, 2007, the DEA issued *an Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007,

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AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration.

(b) On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone.

(c) On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone.

(d) On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone.

(e) On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone.

(f) On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 CFR § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program".

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(g) On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility").

(h) On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone.

(i) On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.

(j) On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

308.

Rather, than abide by these public safety statutes, the Drug-Distributor Defendants,

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individually and collectively through trade groups in the industry, pressured the U.S. Dept. of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.

309.

The epidemic is on-going because the fines and suspensions imposed by the DEA do not change the conduct of the wholesale distributor industry. They pay fines as a cost of doing business in an industry which generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility. And, as bluntly noted by Cardinal Health in its pleadings in *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012), "suspension … will not address the harm DEA alleges because it will not prevent pharmacies filling illegitimate prescriptions from simply obtaining controlled substances from another distributor."

310.

Drug-Distributor Defendants have taken advantage of a lack of DEA law enforcement in Multnomah County and abused the privilege of distributing controlled substances in our community.

311.

Upon information and belief Drug-Distributor Defendants have failed to refuse to stop or supply controlled substances to Multnomah County pharmacies at all times relevant to this lawsuit. Drug-Distributor Defendants are required to ensure that they were not filling

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suspicious orders. Drug-Distributor Defendants' intentional distribution of excessive prescription pain killers to this community showed a reckless disregard to the health and safety of Multnomah County and its residents. The repeated filling of suspicious orders, over an extended period of time, in violation of public health and safety statutes by the Drug-Distributor Defendants demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others.

312.

Drug-Distributor Defendants' failure to monitor, detect, investigate, refuse and report suspicious orders is a direct and proximate cause of the diversion in Multnomah County, Oregon of prescription opiates into the illicit market for inappropriate, improper, and unsafe purposes. Upon information and belief, Drug-Distributor Defendants made little to no effort to visit the pharmacies and drug stores in Multnomah County to which they shipped substantial amount of prescription medication to do due diligence to ensure the medications they were shipping were not diverted to illegal uses. Rather, Drug-Distributor Defendants paid their sales force employees and managers bonuses and commissions on the sale of most or all of the highly addictive prescription pain killers suppled to Multnomah County.

313.

The unlawful conduct by Drug-Distributor Defendants caused the very harm laws were intended to prevent; namely, the diversion of prescription opiates for nonmedical purposes and the poisoning of the community.

314.

The unlawful diversion of prescription opiates is a direct and proximate cause of prescription opiate abuse, addiction, morbidity and mortality in Multnomah County, Oregon.

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315.

Drug-Distributor Defendants made substantial profits from the drugs which were sold in Multnomah County.

316.

Defendant Drug Prescriber, Julie Ann DeMille was the operator of an illegal pill mill in Portland, Oregon. DeMille was indicted by a Multnomah County Grand Jury on July 20, 2016 in *USA v Julie Ann DeMille et al*, 3:16-CR-00312-JO. According to the indictment, DeMille who had a DEA registration number as a nurse practitioner in connection with her job in Clackamas County as a public health nurse, maintained an illegal operation under the assumed business name of "Fusion Wellness Clinic" by which she and one associate, Osasuyi Kenneth Idumwonyi and some 18 co-conspirators (all also indicted) profited from the sale of prescriptions for controlled substances such as OxyContin and Hydrocodone manufactured, distributed, and dispensed by other Defendants in this case. This operation continued at least from the date of DeMille's registration with the Oregon Secretary of State as "Fusion Wellness," on November 10, 2014 - or some 18 months prior to June 20, 2016 - until the date of her indictment on or about July 20, 2016. Among the federal criminal charges against DeMille were: Conspiracy to distribute or dispense and possession with intent to distribute or dispense controlled substances; Conspiracy to distribute or dispense and possession with intent to distribute or dispense a controlled substance; Making a false statement or representation to a department or agency of the U.S.; Distribution and dispensation of a controlled substance.

317.

The indictment charges that DeMille did knowingly and intentionally combine,

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conspire, confederate, and agree with others to distribute or dispense, and possess with intent to distribute or dispense, the Schedule II controlled substances oxycodone and hydrocodone, outside the scope of professional practice and not for a legitimate medical purpose. Demille unlawfully prescribed excessive amounts of controlled substances, knowing that such practice could result in overdoses, dependence, addiction, and, in some cases, death to clinic customers. In many instances, DeMille repeatedly prescribed Co-conspirators and Customers the same excessive dosages of controlled substances regardless of their medical condition.

318.

It was the object of the conspiracy to unlawfully prescribe excessive amount of controlled substances to clinic customers in return for cash payment and for clinic customers to obtain controlled substances for the purpose of unlawful distribution. When a co-conspirator received a prescription for 120 pills of oxycodone at 15 milligrams each, that single prescription would have a street value of approximately $1800. DeMille charged $200 per prescription, then later $250. To maximize profits, large numbers of clinic customers were scheduled on any given day with appointments lasting between 45 and 90 seconds. The primary purpose was to provide a controlled substance prescription to the clinic customers in exchange for a prescription fee. DeMille's share of the proceeds of the operation was approximately $7,000 per week.

H. ***The Opioid Epidemic Remains Unabated in Multnomah County.***

319.

Meanwhile, the opioid epidemic continues in Multnomah County, Oregon Prescription Opioids are highly addictive. The drugs that are driving up the alarming numbers reported in Oregon and Multnomah County are opiates – heroin and prescription

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pain medication. Oregon has the highest rate of opiate abuse among people under age 25 in the United States. More than half of the drug overdose deaths in Oregon are related to prescription opioids such as OxyContin and Vicodin. Between 2000 and 2013 there were 2,226 deaths in Oregon due to prescription opioid drug overdose.

320.

There would have been a continued dramatic increase in the death toll in Multnomah County but for the more than 2,000 Naloxone reversals that were performed.[55]

321.

Oregon consistently ranks near the top among all states in the non-medical use of prescription pain relievers and actually lead the nation in 2010-2011.[56] In 2013, 3.6 million prescriptions for opioid pain killers were dispensed in Oregon, enough for 925 opioid prescriptions for every 1000 residents. More than one in five people in the Tri-County region receives an opioid prescription every year.

322.

Across the Tri-County region in 2015, there were 159 fatal opioid overdoses—two-thirds were in Multnomah County. For every death, there are an estimated 26 non-fatal overdoses and approximately 100 additional people suffering from opioid dependence and addiction. In 2015, there were over 600 overdose responses in Clackamas and Multnomah Counties with 88% in Multnomah County. Over half of those responses were calls to public places or businesses.

[55] Naloxone is the opioid overdose-reversal drug. Multnomah County has trained more than 3,300 people in the safe use and administration of Naloxone.

[56] SAMHSA, *State Estimates of Nonmedical Use of Prescription Pain Relievers*, NATION SURVEY ON DRUG USE AND HEALTH (Jan. 8, 2013) (*available at* http://archive.samhsa.gov/data/2k12/NSDUH115/sr115-nonmedical-use-pain-relievers.htm).

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323.

In 2015, retail pharmacies dispensed over 1.4 million opioid prescriptions to resident of the Tri-County Region which has a population of approximately 1.7 million. Opioid use disorder equals 40% of all substance use disorder claims, separate from alcohol, amphetamines, cocaine, marijuana, etc.[57]

324.

The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addiction.

325.

There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[58] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[59]

326.

People who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin.[60] The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.[61] Consequently, the CDC instructs that they way to

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[57] *Tri-County Opioid Trends*, *Clackamas, Multnomah, and Washington, Oregon* (2016) (*available at* https://portlandprofessional.oregonpainguidance.org/wp-content/uploads/sites/8/2017/02/TRI-COUNTY-REGION-OPIOID-TRENDS-2016-REPORT.pdf).

[58] Dart, MD, et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, NEW ENGL. J. MED., 372:241-248 (January 15, 2015)

[59] Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse*, NEW ENGL. J. MED. (April 14, 2016) (*available at* http://www.nejm.org/doi/full/10.1056/NEJMsr1601307#t=article).

[60] CDC Press Release, *New Research Reveals the Trends and Risk Factors Behind America's Growing Heroin Epidemic*, (July 7, 2015) (*available at* https://www.cdc.gov/media/releases/2015/p0707-heroin-epidemic.html).

[61] CDC, *Today's Heroin Epidemic*, VITAL SIGNS (*available at* https://www.cdc.gov/vitalsigns/heroin/).

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stop the heroine epidemic is to "[a]ddress the strongest risk factor for heroin addiction: addiction to prescription opioid painkillers."[62]

327.

The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.

FIRST CLAIM FOR RELIEF

Public Nuisance

328.

Plaintiff realleges and incorporates by reference paragraphs 1 to 327 above.

329.

Defendants' actions were intentional, reckless, abnormally dangerous, deceitful, or negligent as detailed above and below.

330.

Defendants manufactured, distributed, marketed, and promoted opioids in a manner that created a public nuisance that is harmful and disruptive to health, safety and general welfare of Multnomah County and to a substantial number of its residents.

331.

Defendants knew or should have known that their deliberate and reckless promotion and sale of opioids for widespread use would lead to widespread addiction, abuse and death

[62] *Id.*

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in Multnomah County and would be harmful and disruptive to health, safety and general welfare of Multnomah County and to a substantial number of its residents. In addition, Defendants knew or should have known that their conduct would have adverse and increasingly negative consequences which seriously and unreasonably interfere with quality of life in the Community.

332.

Defendants knew or should have known that their deliberate and reckless promotion and sale of millions of opioids for widespread use in Multnomah County would lead to the type of opioid poisoning and contamination that is currently plaguing Multnomah County.

333.

It was foreseeable to Defendants' that their conduct would seriously and unreasonably interfere with the ordinary comfort, use, and enjoyment of public places by residents of Multnomah County.

334.

The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit. There is no social utility to opioid misuse and any alleged value is outweighed by the gravity of the harm inflicted by Defendants' actions.

335.

Defendants' man-made, profit-driven nuisance has taxed the human, medical, public health, law enforcement, and financial resources of the County.

336.

Defendants' malicious and harmful conduct has affected and continues to affect the County and considerable number of people within the County and is likely to continue to

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cause significant harm.

337.

The public nuisance created, perpetuated, and maintained by Defendants can be abated and further reoccurrence of such harm and inconvenience can be prevented.

338.

Plaintiff has incurred substantial costs from investigating, monitoring, treating, policing and remediating the opioid epidemic.

339.

Plaintiff seeks compensatory damages from these Defendants for the creation of a public nuisance.

340.

Defendants, and each of them, set forth herein caused foreseeable harm to the County and its citizens. The County suffered past economic damages exceeding $100,000,000 and will incur future economic damages exceeding $150,000,000 to abate Defendants' public nuisance—the opioid epidemic.

SECOND CLAIM FOR RELIEF

Abnormally Dangerous Activity

341.

Plaintiff realleges and incorporates by reference paragraphs 1 - 340 above.

342.

Defendants engaged in ultrahazardous or abnormally dangerous activity.

343.

Defendants introduced and legitimized the widespread use of highly addictive opioid drugs for treatment of pain even though there was no scientific basis to justify providing that

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treatment and the known high rate of addiction after limited use.

344.

Given the high rate of addiction, the widespread use of opioids to treat chronic pain invites grave harm upon the community. The full specter of that harm is clearly evidenced by the opioid epidemic currently ravaging communities across the United States—including Multnomah County.

345.

The high likelihood of addiction and limited utility of opioids for treatment of chronic pain means that the risks associated with opioid use cannot be eliminated by the exercise of reasonable care. This fact is clearly demonstrated by the limited use of opioids in medical treatment prior to Defendants' conduct that is the basis of this civil action.

346.

Before Defendants implemented their marketing scheme to create a demand for their opioid products, the specter of addiction and its terrible life altering effects on even a single patient made doctors reticent to prescribe opioids. Consequently, opioid painkillers were primarily administered in hospitals and under the direct supervision of doctors—most often to cancer or terminally ill patients.

347.

Opioids' limited utility and risk of grave harm associated with their use made prescribing rare and unsupervised use nonexistent. Consequently, before Defendants' calculated quest for profits, the use of opioids for medical treatment was extraordinary, exceptional, or unusual.

348.

Defendants acted even though they knew that widespread opioid use created a high

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degree of harm to individual and community health and safety. Defendants intended that public use of their opioid products would become widespread in the community.

349.

Defendants understood that the specter of harm invited by their actions was great: injury or death to the individual addicts, the creation and maintenance of secondary illicit markets for the sale of Defendants products and, when Defendants products are unavailable or too costly, the dramatic increase of secondary illicit markets for heroin and other opiate street drugs.

350.

Defendants eroded patient trust in the medical system, made some doctors unwitting drug dealers, and facilitated unscrupulous doctors to use their position and station to turn medical clinics into pill mills—all to the harm of the community generally.

351.

Defendants' ultrahazardous and abnormally dangerous activities set forth herein caused foreseeable harm to the County and its citizens. The County suffered past economic damages exceeding $100,000,000 and future economic damages exceeding $150,000,000.

THIRD CLAIM FOR RELIEF

Gross Negligence

352.

Plaintiff realleges and incorporates by reference paragraphs 1 - 351 above.

353.

Defendants and each of them knowingly, recklessly, and wantonly participated in a scheme to take highly addictive drugs whose medical uses were traditionally limited to treat only the most serious maladies and to do so only within in a hospital setting because of their

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known dangerous and addictive properties and to push those drugs to be used for chronic conditions that those drugs did not help and to do away with the direct supervision of a doctor.

354.

Scientific research, public health studies medical training, statutes, and regulations all clearly showed the terrible addictive properties of opioids and warned that widespread use would not cure pain but would instead cause greater pain in the lives of patients, their families, and the community.

355.

Defendants knowingly, recklessly, and wantonly ignored the known serious dangers associated with the widespread use of opioids.

356.

Instead of heeding the warning signs of addiction, Defendants used the fact of addiction as the basis for its business model. Defendants not only knew that these drugs were highly addictive, Defendants saw addiction not as an unwanted side effect harmful to the patient but as an opportunity to increase financial benefits to themselves. That is the case because each new patient had the potential to become a captive, repeat customer—a drug addict.

357.

The knowing, reckless, and wanton tortious conduct of Defendants, and each of them, set forth herein caused foreseeable harm to the County and its citizens. The County suffered past economic damages exceeding $100,000,000. The County will incur future economic damages exceeding $150,000,000.

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FOURTH CLAIM FOR RELIEF

Fraud & Deceit

358.

Plaintiff realleges and incorporates by reference paragraphs 1 to 357 above these paragraphs set forth with particularity the actions that are the basis of Defendants' fraud and deceit.

359.

Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiffs and their residents to induce them to purchase, administer, consume, and pay for opioids as set forth in detail above.

360.

Defendants knew or should have known that Plaintiffs would be adversely impacted economically by their misrepresentations in that certain of Plaintiffs' citizens would become addicted to the Defendants' opioids which, in turn, would cause Plaintiff to expend excess funds on police, fire, medical, and other municipal services to care for their citizens and employees, thereby proximately causing Plaintiff's injuries and damages. Therefore, the Defendants owed a duty of care to Plaintiff.

361.

Defendants knew at the time that they made their misrepresentations and omissions that they were false.

362.

Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions and that the use of Defendants' opioid products would

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become widespread and continuous. Defendants intended to deceive Plaintiff.

363.

Plaintiff and its residents reasonably relied upon the Defendants' misrepresentations and omissions and the use of Defendants' opioid products did become widespread and continuous.

364.

Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

365.

Plaintiff suffered actual pecuniary damages proximately caused by Defendants' misrepresentations and omissions of material fact, which include expending additional funds on police, fire, medical, and other public services that Multnomah County otherwise would not have incurred. The County suffered past economic damages exceeding $100,000,000 and will incur future economic damages exceeding $150,000,000.

FIFTH CLAIM FOR RELIEF

Negligence

366.

Plaintiff realleges and incorporates by reference paragraphs 1 - 365 above.

367.

Defendants, and each of them, committed wrongful acts or omissions all of which created a foreseeable risk to Plaintiff and Plaintiff's residents.

368.

Defendants' conduct was unreasonable in light of that risk.

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369.

In addition to the allegations set forth above, Defendants, and each of them, committed wrongful acts or omissions in one or more of the following ways:

(a) Defendants misrepresented the known addictive properties of opioids.

(b) Defendants misrepresented the known health adverse consequences of opioids.

(c) Defendants failed to maintain systems or exercise due diligence regarding suspicious orders.

(d) Defendants failed to detect and prevent diversion of controlled substances.

(e) Defendants failed to investigate or report suspicious orders.

(f) Defendants distributed opioids for non-medical purposes.

370.

The negligence of Defendants, and each of them, set forth herein caused foreseeable harm to the County and its residents. That harm is presently occurring, has continuously occurred in the past and will continue for the foreseeable future. The County suffered past economic damages exceeding $100,000,000. The County will incur future economic damages exceeding $150,000,000.

371.

In addition, Defendants violated rules and regulations put into place for the purpose of protecting the health, safety, and welfare of the public to include Plaintiff and Plaintiff's residents. The violation of such rules and regulations creates a standard of conduct by which Defendants' actions may be evaluated.

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PLAINTIFF PRAYS FOR JUDGMENT AS FOLLOWS:

1. Economic damages in the amount of $250,000,000.00, subject to amendment at or before trial;

2. Prejudgment interest;

3. For Plaintiff's costs and disbursements incurred herein; and,

4. For such further and other relief as the Court deems just, proper and equitable.

Dated this 3rd day of August, 2017.

NICK KAHL, LLC

/s/ Nicholas A. Kahl

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